Biovigilance in the USA: Progress on Recipient Hemovigilance

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Objectives

- Status of Biovigilance in the US
- Introduction to the NHSN Hemovigilance Module
- Needs for Growth and Improvement in US Hemovigilance

Biovigilance efforts in the U.S.

Examples of initiatives

- Blood recipient hemovigilance
  - CDC's National Hemovigilance Module in NHSN
- Blood donor hemovigilance
  - Donor injuries
  - Evaluation of the donor history questionnaire
  - Annual TTI marker data and post donation incidence interview for high risk factors
- National Blood Collection and Utilization Survey (biennial)
- Blood Availability and Safety Information System (BASIS)
- Emerging Infectious Disease Monitoring
  (e.g., Babesia, Dengue, Q Fever, Chikungunya, HHV8, XMRV)
- Organ and tissue transplantation surveillance
  - Disease Transmission Advisory Committee of UNOS/OPTN (for organs)
  - Transplantation Transmission Sentinel Network pilot (for organs and tissues)
  - Efforts to standardize nomenclature and coding to allow traceability

Transfusion reaction reporting: Why do we need hemovigilance in the US?

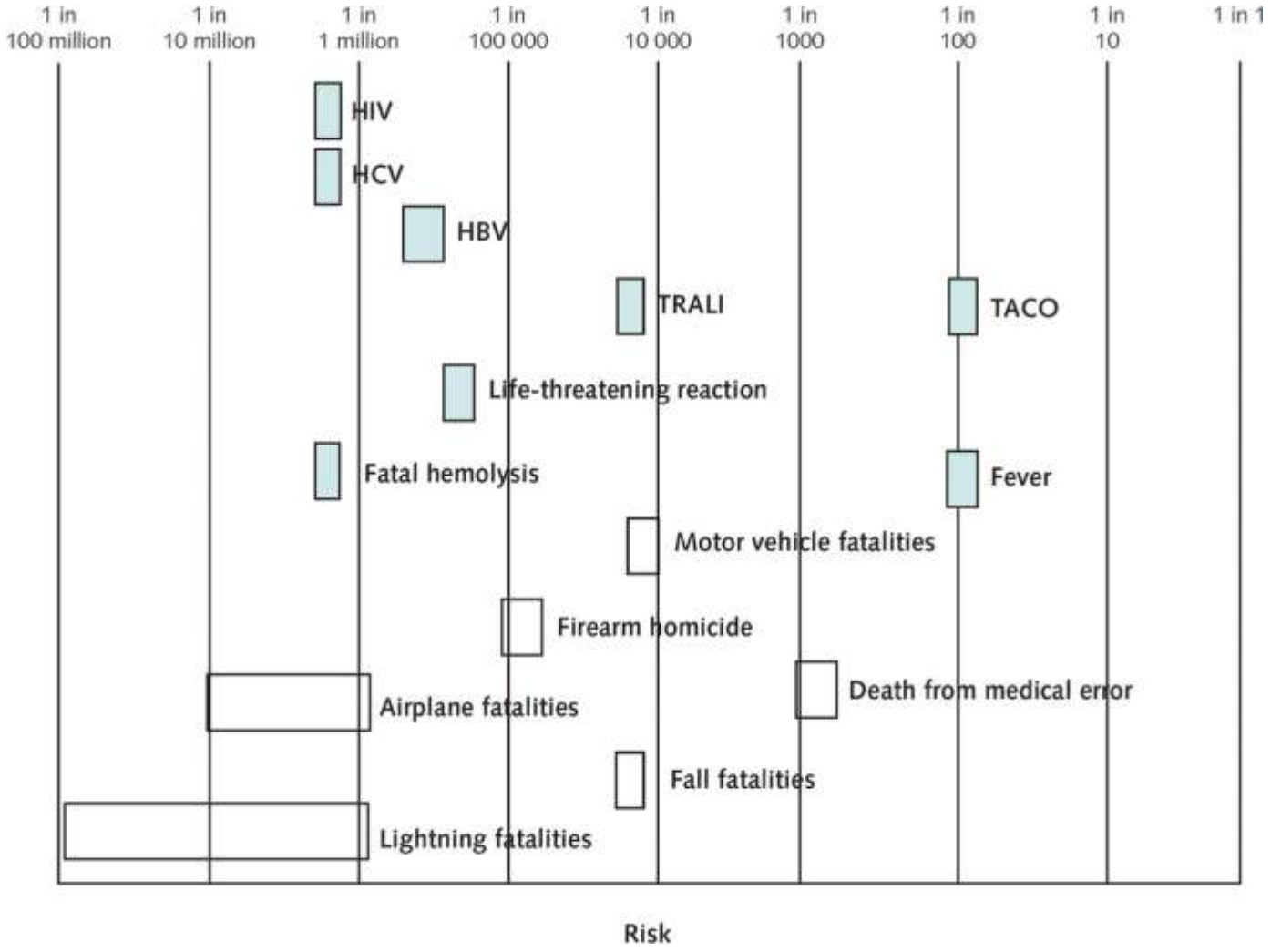
- **Hospital transfusion services and blood centers each have a regulatory burden**
- **FDA – only serious reactions or errors require mandatory reporting , but likely represents a small proportion of what occurs annually**
  - Fatalities – dozens
  - MedWatch – hundreds
  - Biologic Product Deviations – thousands
- **National Blood Collection & Utilization Survey**
  - 70,000+ transfusion reactions annually

Adverse Transfusion Events in the US: How common are they?

Table 7-2. Transfusion-Related Adverse Reactions Reported to the Transfusion Service

Adverse Transfusion Reactions	Number of Occurrences	Reactions: Components Transfused (n=23,669,000 total components)
Total number of reactions that required any diagnostic or therapeutic intervention	60,110	1:394
Febrile, nonhemolytic transfusion reaction	28,997	1:816
Severe allergic reactions	6,555	1:3,611
Delayed serologic transfusion reaction	2,143	1:11,044
Transfusion-associated circulatory overload (TACO)	1,417	1:16,706
Transfusion-associated dyspnea	1,150	1:20,588
Hypotensive transfusion reaction	1,140	1:20,757
Delayed hemolytic reaction	819	1:28,887
Posttransfusion purpura	493	1:47,993
Transfusion-related acute lung injury (TRALI)	460	1:51,443
Acute hemolysis (due to ABO incompatibility)	39	1:606,978
Acute hemolysis (due to other causes)	143	1:164,936
Posttransfusion sepsis	32	1:738,437
Transfusion-associated graft-vs-host disease	0	—
Reactions that were life-threatening, requiring major medical intervention following the transfusion; eg, vasopressors, blood pressure support, intubation, or transfer to the intensive care unit	169	1:139,908

Adverse effects of RBC transfusion contrasted with other risks. Risk is depicted on a logarithmic scale.



Carson J L et al. Ann Intern Med doi:10.1059/0003-4819-156-12-201206190-00429

Annals of Internal Medicine

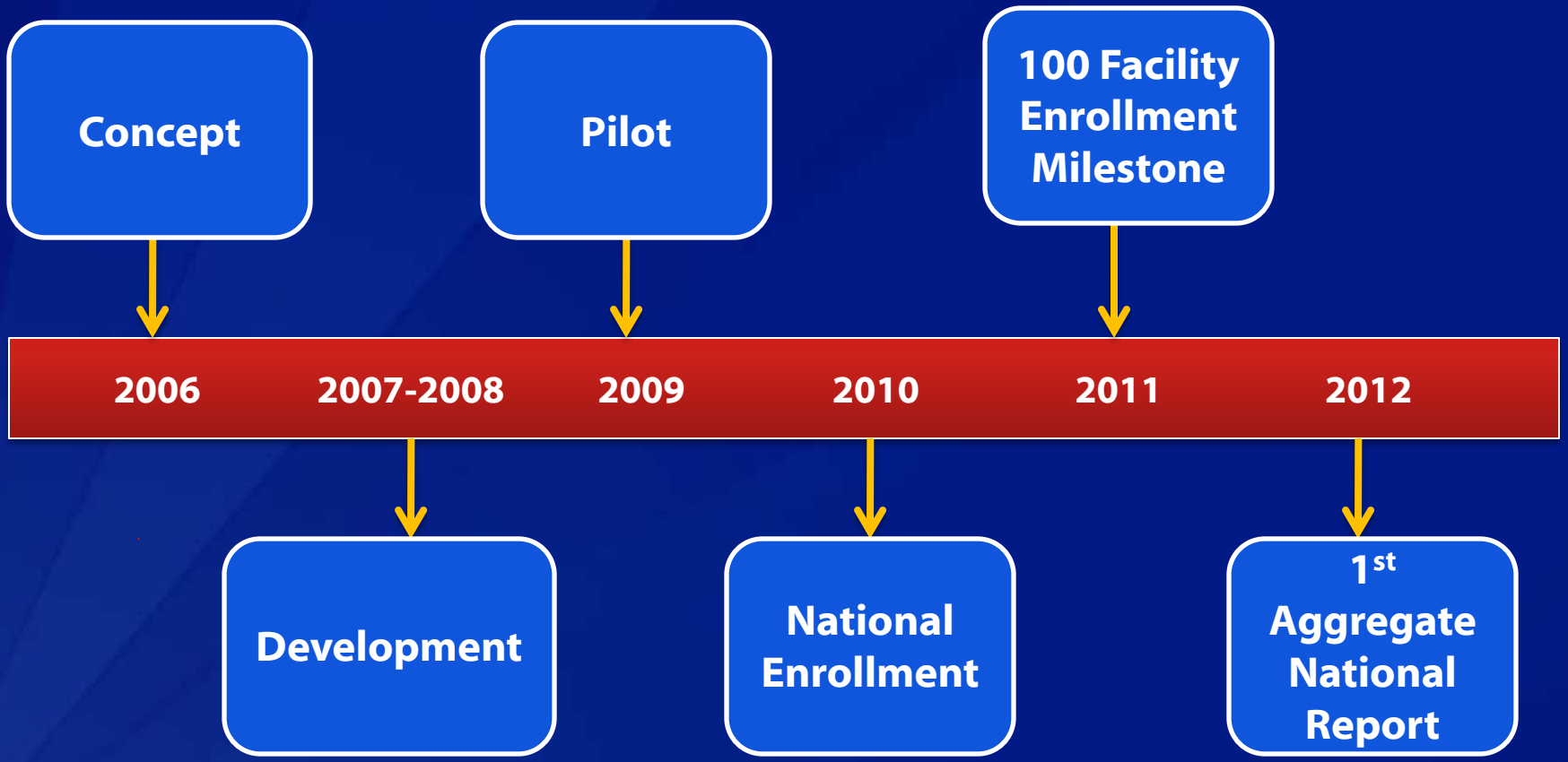
Global Hemovigilance

- **Mature Systems**
  - France, Japan (~1993)
  - UK (1996)
  - Canada (2000) (Quebec in 1997!)
- **Growing Collaboration**
  - "European Hemovigilance Network" as of 1998
  - "International Hemovigilance Network" as of 2006
- **Until 2006, no nationwide "recipient hemovigilance" program existed in the U.S.**

Developing US Recipient Hemovigilance
Public-Private Partnerships

- CDC/HHS
- AABB
- US Transfusion Community

Timeline – 5 years of US Hemovigilance



The National Healthcare Safety Network (NHSN) is a secure, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion (DHQP) at CDC.

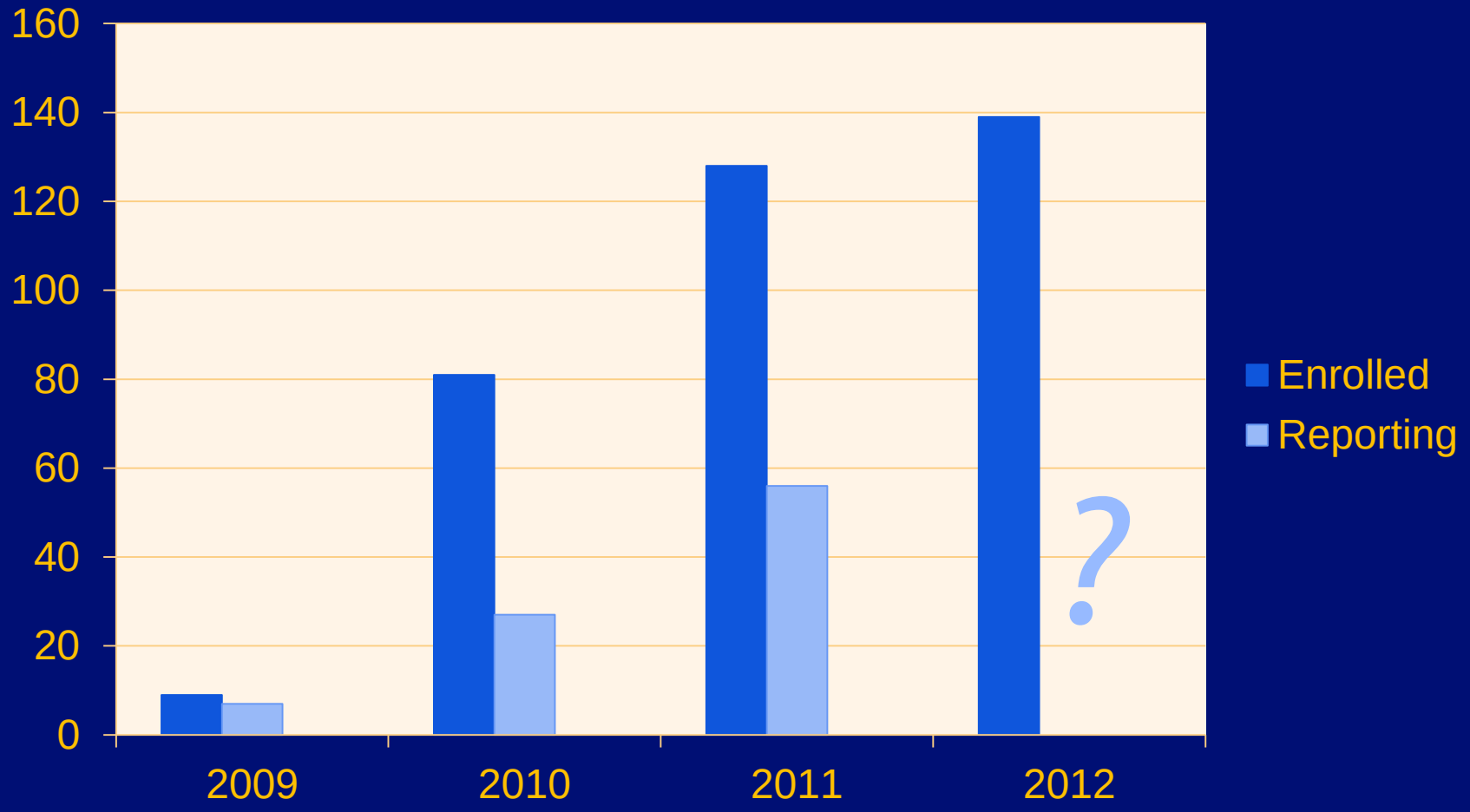
Purposes of NHSN

- **Collect data from participating US healthcare facilities to permit valid estimation of the**
  - Magnitude of adverse events
    - Patient adverse reactions
    - Process incidents
- **Analyze and report collected data to permit recognition of trends in aggregate for comparative purposes**

Why Use NHSN?

- Provides standard definitions, protocols and methodology
- Not just a reporting tool, comparative rates used for performance improvement
- Useful analysis tools are included
- CDC provides training and user support
- Confidentiality
- Ability to share data with other entities using the group function

NHSN Hemovigilance Module Participation
Enrollment vs. Data Reporting



Harvey AR, Kuehnert MJ. Transfusion-Related Adverse Events Reported to NHSN. SCABB Abstract 2012.

Trends in reporting in Canada

From Pierre Robillard, MD

Institut national de santé publique Québec

Challenges: Healthcare facilities have multiple obligations for reporting

- **Voluntary Reporting**
  - NHSN Hemovigilance Module
  - FDA (MedWatch for clinicians)
  - Joint Commission (Sentinel Event)
- **Required Reporting**
  - FDA (for Deaths, Biologic Product Deviations)
  - Facility Q&A
  - Supplying Blood Center
  - State Compliance Authorities

Hemovigilance Data:
Public Health Surveillance vs. Regulatory Reporting
Different paradigms with similar goals

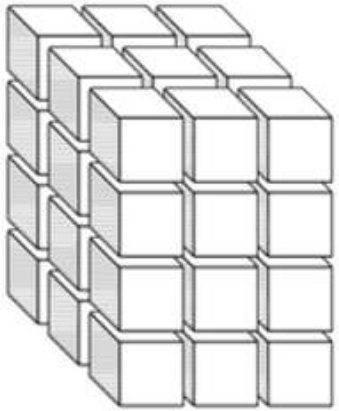
- **Public Health Surveillance**
  - Objective – Improve Outcomes
  - Consensus Based Standards
  - Feedback to Users
  - Benchmarking and Analysis
  - Risk-adjusted Rates
- **Goal: Improve Patient Safety**

- **Regulatory Reporting**
  - Objective – Safe Products
  - Regulation Based
  - Feedback to Regulators
  - Real Time "Sentinel"
  - Numerator Counts
- **Goal: Improve Product Safety**

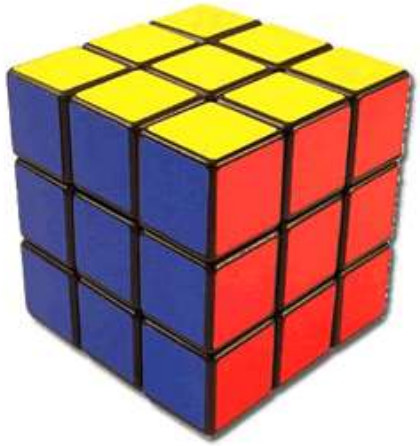
Hemovigilance in the U.S. Current State vs. Ideal State

Current State
"Facility/Industry Centric"

Hospital- or Blood Center-based
Regulatory-based (e.g., FDA, CMS)
Valuable, but limited output



- Common definitions
- Aggregation of data
- Standardized Logic



Ideal State
"Patient Safety Centric"

Tracks safety regardless of data source
Unified public health voice

From Kevin Land, MD (modified)

Cycle for Success in Public Health: Adverse Event Surveillance

Quality Promotion / Adverse Outcome Prevention

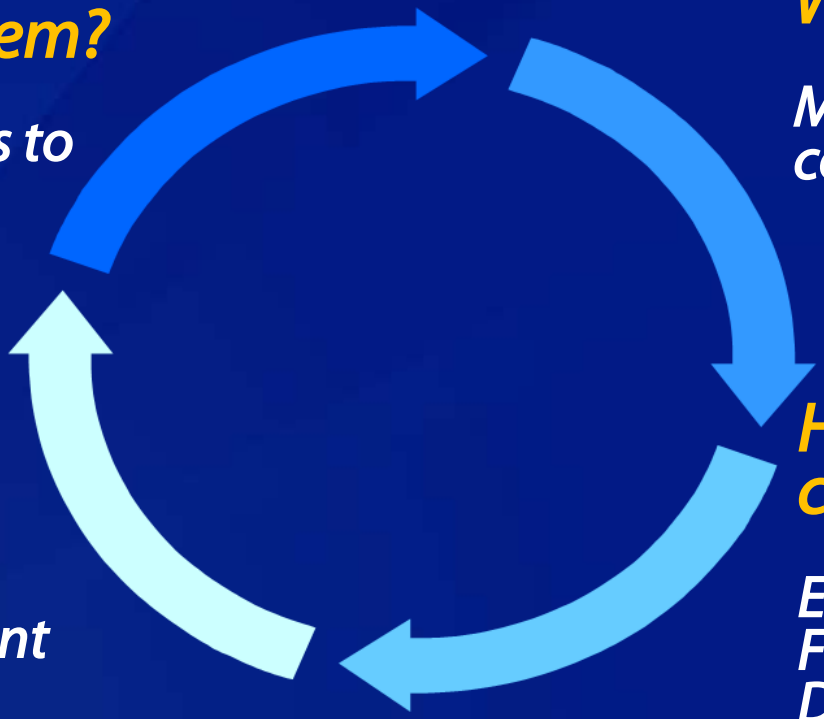
A PUBLIC HEALTH APPROACH, NOT A REGULATORY APPROACH!

Is there an important problem?

Compare local rates to benchmarks

Why? What?

Multi-disciplinary committees



How to affect change?

Education
Feedback
Decision support

Do the changes work?

Monitor progress toward improvement

Use of hemovigilance data to evaluate the effectiveness of diversion and bacterial detection

Pierre Robillard, Gilles Delage, Nawej Karl Itaj, and Mindy Goldman

STUDY DESIGN AND METHODS: Adverse transfusion reactions were reported to the Québec Ministry of Health by transfusion safety officers. Initial aliquot diversion, already in place for apheresis PLTs, was added to all whole blood collections in early 2003. Bacterial detection was implemented in March 2003 for apheresis PLTs and February 2005 for whole blood–derived PLTs (WBDPs).

CONCLUSION: Hemovigilance data demonstrated a highly significant decrease in TTBIs associated with WBDPs, mainly attributed to the implementation of diversion. However, diversion and culture do not totally abolish the risk of TTBIs.

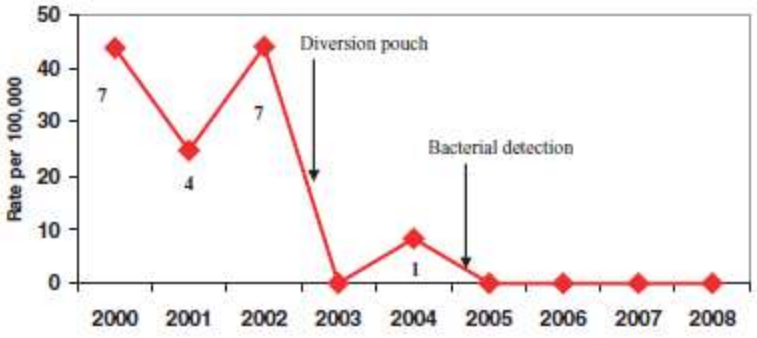
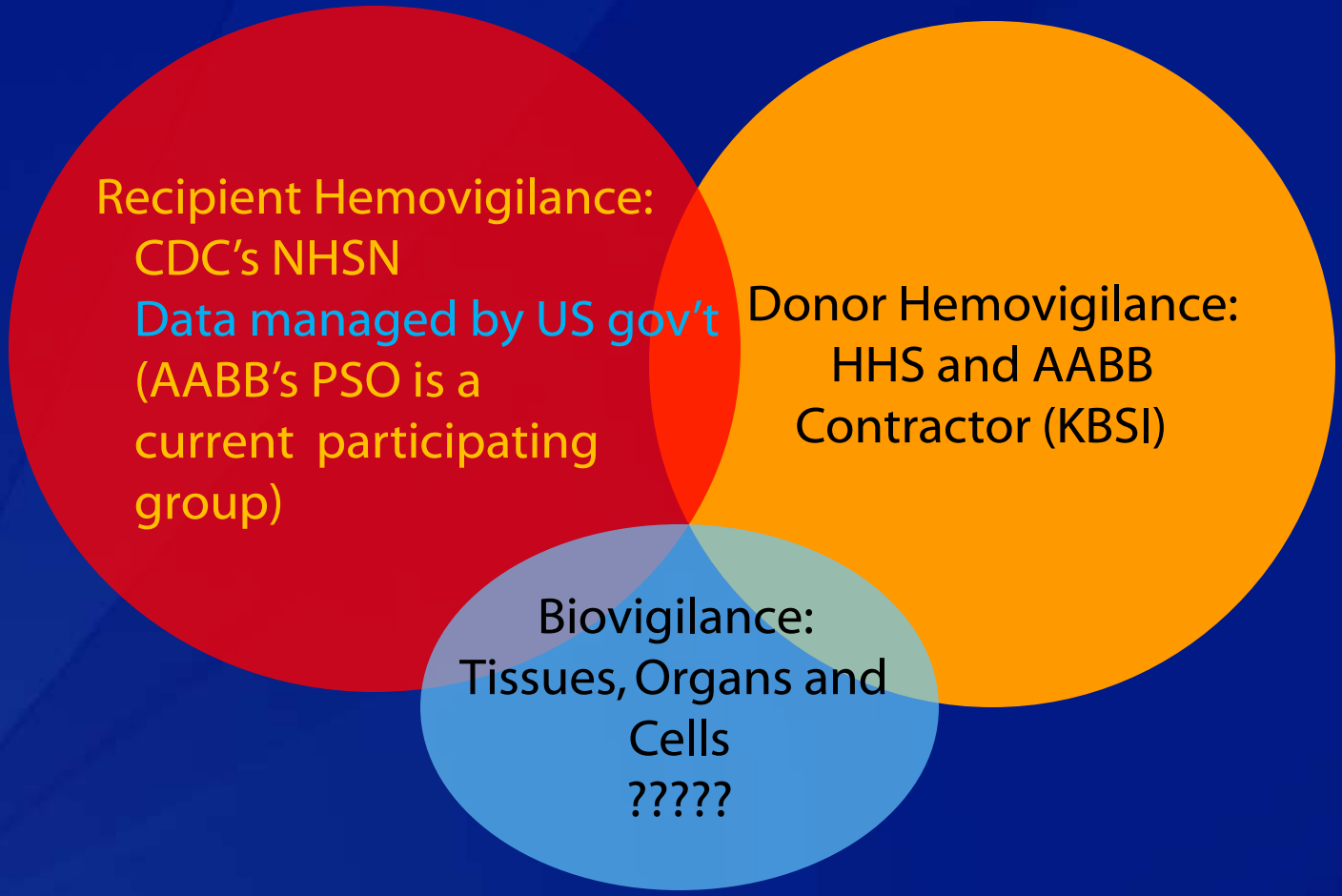


Fig. 1. Annual incidence of TTBIs per 100,000 pools of 5 units of WBDPs. The number of cases and time of implementation of preventive measures are shown on the graph.

P Robillard et al. Transfusion 2011;51:1405-11.

U.S. Hemovigilance: A work in progress



Partners Are Essential

- Federal gov't
- State gov't (health depts)
- Industry
- Trade orgs
- Patient advocacy/consumer orgs
- Accrediting orgs
- Healthcare orgs
- Clinical orgs
- IT companies
- Media
- Community

CDC has partnered within HHS, and external organizations on development of hemovigilance.

CDC NHSN HV Module Steering Group

Responsible for providing input to CDC regarding NHSN Hemovigilance Module surveillance activities, priorities, and plans

- Objectives
  - Developing and maintaining knowledge
  - Input regarding surveillance priorities
  - Forum for feedback regarding prioritization of activities
  - Facilitating input regarding necessary modifications
  - Representing interests and advocating for utilization

- Steering Group members
  - Chair – CDC
    Co-chair - External partner
  - Other CDC representatives
  - Other HHS agencies (Ex-Officio)
  - NHSN Facility Representatives
  - State Health Departments
  - External Partners (e.g., AABB)

To be convened mid-2012…

NHSN HV Module and AABB involvement

- AABB Working Group developed protocol and definitions with CDC during development
- Facilities participating in NHSN can choose to use a "group function" to designate organizations as recipients of confidential facility data, including AABB's Patient Safety Organization
- Groups can perform their own data analyses, which can be separate from overall public health summaries, and lead to surveillance-based intervention

Sharing Data: Groups in NHSN

- **What is a group in NHSN?**
  - A group is a collection of facilities that have joined together within the NHSN framework to share some or all of their data at a single (Group) level for a mutual purpose (e.g., performance improvement, state and/or public reporting).
- **What types of entities can form groups in NHSN?**
  - State Health Departments
  - Quality Improvement Organizations
  - Patient Safety Organizations, e.g., AABB
  - Healthcare Systems
  - Blood Collection Centers
  - Centralized Transfusion Services
- **How are NHSN groups created?**
  - Groups are nominated by existing NHSN Facilities

Sharing Data: Groups in NHSN

- CDC does not send facility data to groups in NHSN.
- NHSN groups obtain data directly from NHSN facilities.
- NHSN groups view and analyze data shared with them but cannot edit, add or delete data.

Opportunities for Groups in NHSN Example: Blood Centers

- Aggregation of adverse events (i.e., adverse reactions, incidents) from facilities that are served by a blood center, allowing comparison to a national aggregate
- Aggregation of denominators for units transfused
- Information on facility demographics

Opportunities and Challenges for Groups in NHSN: Data Analysis and Centralized Transfusion Services (CTS)

- **Surveillance advantages for hemovigilance in CTS model**
  - Better uniformity in application of case definitions across facilities
  - Coordination between facility and blood center on joint investigations of adverse events
  - Support for adverse event reporting

- **Surveillance challenges for hemovigilance in a CTS model**
  - Reporting location of an incident
  - Ascribing an incident to a participating healthcare facility if the CTS is performing the function
  - Variability in the operation of different CTS models means multiple potential solutions for location "mapping" of an incident

Role of the Transfusion Safety Officer (TSO)

- **Examples of blood centers employing a TSO include**
  - Community Blood Center/Community Tissue Services, Dayton OH
  - BloodCenter of Wisconsin
  - Puget Sound Blood Center, Seattle, WA

- **Innovative approach to promote transfusion safety across organizations**
  - Transfusion medicine expertise
  - Blood utilization review
  - Assistance in recognizing transfusion adverse events and encouraging data reporting

Slapak et al. Transfusion Safety: Is this the business of blood centers? JBSM 2011; 51: 2767-2771.

Summary

- **National Hemovigilance in the U.S. is underway**
- **Further efforts will be needed to encourage participation and reporting of quality data**
- **Partnering in specific areas**
  - Educating healthcare facilities on importance of hemovigilance and recruitment into NHSN
  - Facilitating reporting to multiple entities on adverse events in transfusion (e.g., NHSN, regulatory entities, blood centers)
  - Analyzing collected data to improve patient outcomes through interventions that prevent transfusion adverse events

Office of Blood, Organ, and Other Tissue Safety

Resources

http://www.cdc.gov/bloodsafety

http://www.cdc.gov/nhsn/bio.html

Questions?

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nhsn@cdc.gov